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10/758,147	01/14/2004	Nancy G. Pile	29877.702.201	5766

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EXAMINER

GEHMAN, BRYON P

ART UNIT	PAPER NUMBER
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3728

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01/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/758,147

Applicant(s)

PILE, NANCY G.

Examiner

Bryon P. Gehman

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/04</u> . | 6) <input type="checkbox"/> Other: _____ |

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2, "the label" lacks antecedent basis.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 9-13 and 15-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Weinstein et al. (7,156,089)(Figures 2 or 3). Claims 1-3, 11-17 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Bindford (2005/0109658). Claims 1-3 and 9-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Weinstein (6,651,816)(Figure 2 or Figure 4). Claims 1, 9-15, 18-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Koesterman et al. (2003/0211627). Claims 1-3

and 9-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (6,543,616). Claims 1-3 and 9-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstein et al. (5,830,490). Claims 1-4, 11-17, 20-22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Henkin (3,743,088). Each discloses a method and kit comprising disposing a plurality of different drugs (20, 22, 26; 102; inside 22 and 24, or 32 and 34; 50; inside 12; in 2', 3' and 3"; in each 26; respectively) in corresponding drug compartments (receiving the receptacles of 20, 22 and 27; 108; receiving 22 and 24 or 42 and 44; 40; 12; receiving 2', 3' and 3"; receiving each 26) within a container (10; 100; 20 or 40; 10; 10; 1; 20), and providing drug identification information (at 30; on 106; 26 or 46 or 48; 60; at 16; at 5 and 6; at 38) associated with each compartment.

As to claims 2 and 16, all but Koesterman et al. disclose labels (at 30; at 106; at 26 or 46 or 48; at 16; at 5; at 38), a label being an identifying indicia.

As to claims 3 and 17, all but Koesterman et al. disclose the drugs meant to be used in conjunction in some manner.

As to claim 4, Henkin discloses a flexible compartment that alters in shape during the disposing step.

As to claims 9-10 and 18-19, the Weinstein et al. references, Koesterman et al. and Henkin each disclose a drug delivery tool (aerosol units; ancillary devices; aerosol unit; dispensing tubes) disposed in an order of use.

As to claim 11-12 and 20-21, each discloses the drug compartments arranged in an intended order of use with drug identification information arranged to demonstrate the intended order of use.

As to claim 13-14 and 22, the drug information of each discloses the information labeling the container, with each also disclosing labeling instructions on a lid (12;106; at 28 or 48; 20; at 16; 7; 28).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of the art as applied to claim 15 above. To modify the dimensions of any of the previously employed references to that of the ranges as claimed would at most entail a mere change in size or shape of the kit and yield only predictable results, as the change in size and shape of the prior art does not distinguish any new or unexpected result. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless

its actual application is beyond that person's skill." *KSR Int'l v. Teleflex Inc.*, 127 S.Ct. 1740, 82 USPQ2d 1396 (2007).

7. Claims 4-6 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the art, except Bindford, as applied to claims 1 and 15 above, and further in view of any one of Kogen (6,126,010), Dixon (2,542,640) and Henderson (1,644,830). The prior art references employed each disclose a compartmented drug container, but except for Henkin not a drug compartment being altered in size during disposing of drugs within the container. Kogen, Dixon and Henderson each disclose providing a container with drug compartments (defined by 54; defined by 19 and 20; defined by 17-26) which can be altered prior to completion of a disposing step associated therewith. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide any one of the base references with adjustable compartments as claimed, as such a modification would predictably allow the storage of drug containers of various sizes in the manner suggested by any one of Kogen, Dixon and Henderson. "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int 'l v. Teleflex Inc.*, 127 S.Ct. 1731, 82 USPQ2d at 1396.

8. Claims 7-8 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the art as applied to claims 4 and 26 above, and further in view of Orthwine (1,739,730). The references previously employed do not disclose the addition of a false

bottom to compartments. However, Orthwine discloses providing an adjustable false bottom (16, see page 2, lines 37-62) to a compartmented container in order to render the compartments of adjustable depth according to the contents to be received.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bindford in view of Farukhi (3,286,905). The kit container of Bindford has been explained above, and does not disclose a tab. However, Farukhi discloses associating a tab (14) with a container (10) to facilitate the container removal from a mailing container (22). To dispose the kit container of Bindford in a mailing container as taught by Farukhi would have been obvious in order to facilitate mailing of the kit container as suggested by Farukhi, the use of a particular container not providing any new or unobvious result from the general disclosure of Farukhi that would apply to various types of container as the inner container.

10. Claims 15 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (5,011,020) in view of either one of Henkin and Whitcher et al. (4,195,059). Stevens et al. disclose a kit container comprising a plurality of compartments (40), and a plurality of different drugs disposed in the compartments, and a biohazard container (22) disposed in the kit container. Stevens et al. do not disclose information provided on the container. Henkin and Whitcher et al. each disclose disposing drug identification information (at 16; 26-29) associated with each compartment of a drug kit container. To modify the kit container of Stevens et al.

employing drug identification information as disclosed by either one of Henkin and Whitcher et al. would have been obvious in order to provide information to a user of the kit container, as generally disclosed by Henkin and Whitcher et al..

11. This application contains claims directed to the following patentably distinct species: I) Figures 1-3; II) Figure 4; and III) Figure 5. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims appears generic and allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that a reply to this requirement must include i) an identification of the species to be examined even though the requirement may be traversed (37 CFR 1.143) and ii) identification of the claims encompassing the

elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Tuesday through Thursday from 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bryon P. Gehman
Primary Examiner
Art Unit 3728

BPG